**23230. Misbranding of Pheno-Isolin. U. S. v. 10 Bottles of Pheno-Isolin. Default decree of condemnation and destruction.** (F. & D. no. 31092. Sample no. 43036–A.)

This case involved a shipment of a drug preparation, the labeling of which contained unwarranted germicidal, curative, and therapeutic claims.

On September 14, 1933, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 10 bottles of Pheno-Isolin at Jersey City, N. J., alleging that the article had been shipped in interstate commerce, on or about August 23, 1933, by the Scientific Manufacturing Co., Inc., from Scranton, Pa., and charging misbranding in violation of the Food and Drugs Act as amended.

Analysis showed that the article consisted essentially of turpentine, camphor, menthol, and resin dissolved in an oil. Bacteriological examination showed that it required many hours' contact with bacteria before it exerted any germicidal action. Tests also showed that it was not an antitoxin.

The article was alleged to be misbranded in that the following statements on the label and circular were misleading, since many of the directions were for use under conditions of brief contact, where it would not be germicidal: (Label) "Germicide"; (circular) "Germicidal Test Method—F. D. A. Wet Filter Paper. U. S. Dept. of Agriculture Circular 198. December, 1931. Organism—Staph. aureus. F. D. A. Culture No. 209. Age of culture—24 hours at 37 degrees C. Medium—Standard broth. Peptone—Armours Special. Organic matter—None. Temperature of medication—37 degrees C. Sterile 0.5 cm. squares of Whatman's No. 2 filter paper were impregnated with Staph, aureus having the standard resistance to phenol at 37 degrees C. The wet impregnated papers were then immersed in the sample under test and a paper square removed at stated intervals and retransferred to 10 cc. of sterile broth, washed by agitation and use of a sterile needle, and transferred to a second 10 cc. of sterile broth. Both sets of tubes were then incubated at 37 degrees C. for 48 hours with the following results:

| | Hours of Exposure | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sample | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Pheno-Isolin Undiluted | + | + | + | + | + | + | + | + | − |

| | Minutes of Exposure | | |
|---|---|---|---|
| | 5 | 10 | 15 |
| Phenol 1:80 | + | − | − |
| 1:90 | + | + | + |

"Comments: These results show that Pheno-Isolin has germicidal action in a nine hour period of exposure under the conditions of the test. * * * In the germicidal test, the Pheno-Isolin is slowly absorbed by the bacteria, as the Pheno-Isolin is very slowly soluble in aqueous solutions, which, of course, are different from the albuminous serum in the wound or toxin compounds."

Misbranding was alleged for the further reason that the following statements regarding the curative and therapeutic effects of the article were false and fraudulent: (Carton) "Prevents and destroys infection A Local Antitoxin"; (circular) "How to prevent and destroy infection * * * Pheno-Isolin is the only local-antitoxin that has ever been produced * * * It is especially recommended in preventing and treating infection, and many cases of years standing have been successfully treated with Pheno-Isolin. * * * relief from pain, especially so if due to infection. * * * Pheno-Isolin is no doubt the only preparation recommended to destroy infection, because it is the only local-antitoxin made. Many preparations attempt to kill bacteria outright, but also kill some tissue at the same time. The dead tissue decomposes, and forms excellent food for bacteria. The most important point in destroying infection is entirely overlooked by all other preparations. Although bacteria often develop rapidly in an infected area, they are also short lived. When these bacteria die, they form a powerful poison called 'toxins.' It is these poisons that cause pain, swelling, fever, and often tetanus or lock-jaw when they enter the circulation. Pheno-Isolin is the only preparation that neutralizes these toxins or poisons, as it is the only local-antitoxin. In neutralizing these poisons, they are made harmless, and so do not enter the circulation. When Pheno-Isolin is used in infected cases, this property is most apparent, as the patient usually experiences relief from pain, swelling goes down and the fever disappears, often beginning within two hours after it is used. This can be accomplished only by a local antitoxin. * * * eliminates bacteria by a solvent action. * * * is highly recommended for sore mouths, sore gums and sore throat. * * * It has

been found to be very effective for coughs * * * especially bronchial cases. Covers the wound with a protective film, making it impossible for after infection to occur. In cases of infection or ulcers, Pheno-Isolin should be applied at least twice daily. It is important that all parts of the affected area be reached with the local-antitoxin, so as to neutralize the toxins and destroy the bacteria * * * General directions * * * Boils and Carbuncles: * * * used twice a day until the infection is brought under control. * * * Infection, Ulcers, Bed Sores, Etc.: * * * In badly infected cases or old ulcers * * * Sore Throat: * * * Sore Gums, Pyorrhea, and Mouth Ulcers: * * * Ulcerated Cancer: * * * pack the ulcerated part with gauze well soaked with Pheno-Isolin, using bandage to keep in place. * * * This will relieve the itching and burning and give the patient great relief. For Skin Affections, * * * Neuritis: * * * Ear Infections * * * For Coughs."

On September 7, 1934, no claimant having appeared, judgment of condemnation was entered and destruction of the product was ordered.

M. L. WILSON, *Acting Secretary of Agriculture.*

**23231. Adulteration and misbranding of compound solution of iodine, acetanilid tablets, and fluidextract of ergot. U. S. v. Meyer Bros. Drug Co. Plea of nolo contendere. Fine, $350.** (F. & D. no. 31315. Sample nos. 15608–A, 15633–A, 34092–A.)

This case was based on shipments of compound solution of iodine and fluidextract of ergot which were represented to be of pharmacopoeial standard, and a shipment of acetanilid tablets which were represented to contain 5 grains of acetanilid per tablet. Examination showed that the compound solution of iodine and the fluidextract of ergot fell below the standard provided in the United States Pharmacoepoeia, the former containing less iodine than required and less than declared on the label; and the latter having a potency of less than one fifth the pharmacopoeial requirement; and that the acetanilid tablets contained less than 5 grains of acetanilid. The fluidextract of ergot, because of its low potency, would not produce the therapeutic effects claimed on the label, when used according to directions.

On March 29, 1934, the United States attorney for the Eastern District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Meyer Bros. Drug Co., a corporation, St. Louis, Mo., alleging shipment by said company in violation of the Food and Drugs Act as amended, on or about May 4, 1932, from the State of Missouri into the State of Indiana, of a quantity of acetanilid tablets; on or about July 30, 1932, from the State of Missouri into the State of Illinois, of a quantity of compound solution of iodine; and on or about February 15, 1933, from the State of Missouri into the State of Arkansas, of a quantity of fluidextract of ergot; which said products were adulterated and misbranded. The articles were labeled: "Compound Solution Of Iodine Lugol's (Liquor Iodi Compositus U. S. P. X) An Aqueous solution containing: Iodine 5 percent"; "Tablets Acetanilid 5 Grains"; "Fluidextract Ergot U. S. P. * * * One Cc. of this Fluidextract represents one gramme of superior Standard Ergot * * * Meyer Brothers Drug Co. Saint Louis."

The compound solution of iodine and the fluidextract of ergot were alleged to be adulterated in that they were sold under and by names recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said pharmacopoeia official at the time of investigation in that the former contained less than 4.8 grams of iodine per 100 cubic centimeters, namely, not more than 4.39 grams of iodine per 100 cubic centimeters, equivalent to 4.39 percent of iodine; whereas the pharmacopoeia provides that compound solution of iodine shall contain not less than 4.8 grams of iodine per 100 cubic centimeters; the latter had a potency of less than one fifth of that required by the said pharmacopoeia for fluidextract of ergot; and the standard of strength, quality, and purity of the articles was not declared on the containers. Adulteration was alleged with respect to all products in that their strength and purity fell below the professed standard and quality under which they were sold, in the following respects: the compound solution of iodine was represented to conform to the standard laid down in the pharmacopoeia, tenth revision, and to contain 5 percent of iodine; whereas it did not conform to the pharmacopoeial standard and contained less than 5 percent of iodine, namely, not more than 4.39 percent of iodine; the acetanilid tablets were represented to contain 5 grains each of acetanilid, whereas they contained not more than 3.6 grains of acetanilid per tablet; and